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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/658,247

09/08/2003

John W. Dohner

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04/21/2005

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EXAMINER

HOWARD, SHARON LEE

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/658,247

Applicant(s)

DOHNER ET AL.

Examiner

Sharon L. Howard

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Applicant's arguments filed on 12/14/04 have been fully considered and are persuasive. The double patenting rejection under 35 U.S.C. 101 has been withdrawn and upon further consideration, a new grounds of rejection under 35 U.S.C. 102(b) is made over the Braun ('928) reference. Receipt of the amendment, the remarks, one month extension of time and the declaration under Rule 1.131 filed on 12/14/04 have been acknowledged.

Status of the Claims

The objection to claim 29 has been overcome. Claims 27, 29 and 32 are currently amended. New claims 33-38 have been added. Claims 27-38 are now pending in this application.

The declaration filed on 12/14/04 under 37 CFR 1.131 has been considered but it does not submit scientific evidence to show that applicant has possession of the process currently claimed. Statements should be supported by evidence that establish the process prior to the invention of the Braun ('928) reference.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-32 and the newly added claims 33-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Braun (USPN 5,662,928).

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Braun meet the claims of the instant application. Braun teaches the same method for producing a scopolamine free base containing transdermal system substantially free of crystals of hydrated scopolamine free base, comprises annealing scopolamine free base containing layers of the transdermal system at a temperature of at least 67 degrees Celsius for about 5 minutes to about 15 minutes within about 24 hours of casting a scopolamine free base onto a web for use in constructing the transdermal system (see the abstract and see claim 1 at col.4). Braun teaches that annealing takes place for a scopolamine containing contact adhesive layer and a drug reservoir layer containing scopolamine free base and a contact adhesive layer containing scopolamine free base are each separately annealed and then contacted and sealed together, then contacted and further annealed prior to packaging (see claims 15,16,17 and 18). Braun teaches the same method for manufacturing delivery devices for the transdermal administration of scopolamine (see claim 19, col.6).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

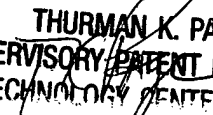
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon Howard
April 13, 2005



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 16